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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,730	05/03/2006	Nicholas Dale	46309-315846	9069
23370 7590 03/25/2010 JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309				
EXAMINER SAKELARIS, SALLY A				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
03/25/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/540,730

**Applicant(s)**

DALE ET AL.

**Examiner**

SALLY A. SAKELARIS

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-29 and 31-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29 and 31-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment filed 1/15/2010 has been received and considered for examination.  
Claims 26-29 and 31-49 remain pending.

### ***Claim Interpretation***

As to pending claims, 26-29 and 31-49 below, which contain intended use terms, the Examiner will interpret these claims in light of the structural elements that are disclosed and not for their intended use as stated after the phrase "obtainable by/from". The phrase, "obtainable by/from" is a product by process limitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be made or employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Exparte Masham*, 2 USPQ2d 1647 (1987). The Examiner has applied references, which are capable of meeting these functions. A structure, which is capable of providing the intended use or a structure that is the same as the claimed product by process of making, is considered to meet the limitation of intended use recited in a claim to a device or an apparatus.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Analytica Chimica Acta 388 (1999) 71-78).

With regard to claim 26, Zhang et al. teach a functionalized inorganic-organic composite material derived by sol-gel for construction of mediated amperometric hydrogen peroxide biosensor. With regard to applicant's recitations of process steps applicant is reminded that where one claims a composition by reference to the process by which it is produced, his protection is limited to compositions produced by the process recited in the claim Purdue Research Foundation v. Watson, Comr. Pats. (DCDC 1958) 742 OG 616, 122 USPQ 445; Smith v. Goodyear Vulcanite Co. (USSC 1877) 93 US 486, 23 L Ed. 952. In ex parte situations, product-by process claims are not construed as limited to the product formed by the specific process recited. In re Hirao et al. (CCPA 1976) 535 F2d 67, 190 USPQ 15. Therefore, process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. In re Thorpe et al. (CAFC 1985) 771 F2d 695, 227 USPQ 464; in re Dike (CCPA 1968) 394 F2d 584, 157 USPQ 581; Tri-Wall Containers, Inc. v. U.S. (Ct Cls 1969) 408 F2d 748, 161 USPQ 117; In re Brown et al. (CCPA 1972) 450 F2d 531, 173 USPQ 685; Ex parte Edwards et al. (BPOAI 1986) 231 USPQ 981.

With regard to claim 27, Zhang et al. teach an electrically conductive substrate (See 2.3 preparation of modified electrode, pg. 73). With regard to applicant's recitation of a electrically conductive substrate being a microelectrode, Zhang's teaching of their biosensor consisting of an electrode is being interpreted as a microelectrode because of its ability to detect microscopic levels of a substance, ie.,  $\mu\text{M H}_2\text{O}_2$  (Top left Pg. 78).

With regard to claim 28, while it is maintained that the limitations of a product by process claim are full met by minimally teaching the claimed structure, Zhang et al. teach a

device where the sol-gel was obtained through a reaction comprising 3-Mercaptopropyltrimethoxysilane (MPTMS).

With regard to claim 29, a BAS100B/W potentiometer is taught (Pg. 72 right hand side).

With regard to claims 31-37, applicant's claims include only process steps and intended uses for their biosensor instead of structural limitations of the biosensor itself. As such the structure of Zhang that is comprised of Horse Radish Peroxidase (HRP) for example, is capable of functioning and being used as claimed.

With regard to claims 38-44 and 47, Zhang et al. teach their sol-gel was obtained through a reaction comprising 3-Mercaptopropyltrimethoxysilane (MPTMS) and to therefore contain an alkoxyisilane and furthermore a MeTMOS (Pg. 72, right side).

With regard to claims 45, 46, 48, and 49, these claims recited process steps involved in the making of the biological assay device, as mentioned previously these steps are not considered patentable subject matter in a claim to the product itself. Applicant should amend their claims to positively recite the structural limitations of the device itself versus the method of making the device or the intended uses of the device.

### ***Response to Arguments***

Applicant's arguments with respect to claims 26-29 have been considered but are moot in view of the new ground(s) of rejection.

Furthermore, applicant should note that their arguments are not convincing given their relatedness to the method of making the biosensor instead of to the structure of the biosensor itself. Applicant argues:

*The article by Zhang et al discloses the production of a biosensor utilizing a relatively large glassy carbon electrode (GCE). As shown in paragraph 2.3 on page 73 of Zhang, the glassy carbon electrode was coated with a drop of the sol-gel mixture and left for at least 24 hours at +4°C in a refrigerator. This allows the sol-gel to dry. Applicants respectfully assert that Zhang's technique produces inconsistent results and lacks the uniformity of the deposited sol-gels produced by the presently claimed methods.*

*Zhang's method requires the presence of a copolymer of polyvinyl alcohol grafted with 4-vinyl pyridine. It is this copolymer that allows the attachment of the material to the GCE. That technique is very specific for GCE-type electrodes and would not be suitable for, for example, platinum or other materials. Applicants respectfully assert that the presence of that hydrophobic copolymer alters the structure of the sol-gel material. Applicants further respectfully assert that the way that the material is deposited means that the material is physically distinguishable from sol-gels electrodeposited by the methods of the presently claimed invention.*

Applicant is reminded that where one claims a composition by reference to the process by which it is produced, his protection is limited to compositions produced by the process recited in the claim Purdue Research Foundation v. Watson, Comr. Pats. (DCDC 1958) 742 OG 616, 122 USPQ 445; Smith v. Goodyear Vulcanite Co. (USSC 1877) 93 US 486, 23 L Ed. 952. In ex parte situations, product-by process claims are not construed as limited to the product formed by the specific process recited. In re Hirao et al. (CCPA 1976) 535 F2d 67, 190 USPQ 15. Therefore, process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. In re Thorpe et al. (CAFC 1985) 771 F2d 695, 227 USPQ 464; in re Dike (CCPA 1968) 394 F2d 584, 157 USPQ 581; Tri-Wall Containers, Inc. v. U.S. (Ct Cls 1969) 408 F2d 748, 161 USPQ 117; In re Brown et al. (CCPA 1972) 450 F2d 531, 173 USPQ 685; Ex parte Edwards et al. (BPOAI 1986) 231 USPQ 981.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SALLY A. SAKELARIS whose telephone number is (571)272-6297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS                                    /Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797  
3/22/2010